

4

Notice of Allowability	Application No.	Applicant(s)	
	09/360,685	COVACCI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' amendment filed 06/22/06.
2. ☒ The allowed claim(s) ~~is/are~~ 40, 41, 45, 54, 57, 59, 62, 63, 68, 70, 78, 80, 81, 88, 123, 127, 140-169 and 172-180, now renumbered as claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17-46 and 47-55 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/256,848.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>892- Pap. 40 (1 page).</u> |

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendments

1) Acknowledgment is made of Applicants' amendments filed 10/12/05, 02/16/06 and 06/22/06 in response to the non-final Office Action mailed 07/28/05. With these, Applicants have amended the specification, sequence listing, and the claims.

Examiner's Amendment

2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Mr. Patrick Farley in a telephonic interview on 05 July 2006.

This application has been amended as indicated below:

The specification of the instant application has been amended as indicated below.

The paragraph beginning at line 12 of page 6 of the specification is replaced with the following:

--The "Cytotoxin Associated Immunodominant" (CAI) antigen refers to that protein, and fragments thereof, whose amino acid sequence is described in FIG. 4 and derivatives thereof. The CAI antigen is about 130 kDa as determined by SDS/polyacrylamide gel electrophoresis and comprises the following amino acid sequence (SEQ ID NO: 25):

1 LysAsnGlyLysAsnLysAspPheSerLysValThrGlnAlaLysSerAspLeuGluAsn 20
21 SerValLysAspValIleIleAsnGlnLysValThrAspLysValAspAsnLeuAsnGln 40
41 AlaValSerValAlaLysAlaThrGlyAspPheSerArgValGluGlnAlaLeuAlaAsp 60
61 LeuLysAsnPheSerLysGluGlnLeuAlaGlnGlnAlaGlnLysAsnGluSerLeuAsn 80
81 AlaArgLysLysSerGluIleTyrGlnSerValLysAsnGlyValAsnGlyThrLeuVal 100
101 GlyAsnGlyLeuSerGlnAlaGluAlaThrThrLeuSerLysAsnPheSerAspIleLys 120
121 LysGluLeuAsnAlaLysLeuGlyAsnPheAsnAsnAsnAsnAsnGlyLeuLysAsn 140
141 GluProIleTyrAlaLysValAsnLysLysLysAlaGlyGlnAlaAlaSerLeuGluGlu 160
161 ProIleTyrAlaGlnValAlaLysLysValAsnAlaLysIleAspArgLeuAsnGlnIle 180
181 AlaSerGlyLeuGlyValValGlyGlnAlaAlaGlyPheProLeuLysArgHisAspLys 200
201 ValAspAspLeuSerLysValGlyLeuSerArgAsnGlnGluLeuAlaGlnLysIleAsp 220

Serial Number: 09/360,685
Art Unit: 1645
June 2006

221 AsnLeuAsnGlnAlaValSerGlu 228

SEQ ID NO: 25 is the protein encoded by the nucleotides 7 to 690 of the sequenced DNA having the following nucleotide sequence of SEQ ID NO: 27, wherein the uppercase letters represent the cloned nucleotide sequence of SEQ ID NO: 26 and the lower case letters represent the EcoRI site:

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1   gaattcAAAAATGGCAAAAATAAGGATTTTCAGCAAGGTAACGCAAGCAAAAAGCGACCTT 60
61  GAAAATTCGGTTAAAGATGTGATCATCAATCAAAGGTAACGGATAAAGTTGATAATCTC 120
121 AATCAAGCGGTATCAGTGGCTAAAGCAACGGGTGATTTTCAGTAGGGTAGAGCAAGCGTTA 180
181 GCCGATCTCAAAAATTTCTCAAAGGAGCAATTGGCCCAACAAGCTCAAAAAAATGAAAGT 240
241 CTCAATGCTAGAAAAAATCTGAAATATATCAATCCGTTAAGAATGGTGTGAATGGAACC 300
301 CTAGTCGGTAATGGGTATCTCAAGCAGAAGCCACAACCTTTTCTAAAAACTTTTCGGAC 360
361 ATCAAGAAAGAGTTGAATGCAAACTTGGAAATTTCAATAACAATAACAATAATGGACTC 420
421 AAAAACGAACCCATTTATGCTAAAGTTAATAAAAAGAAAGCAGGGCAAGCAGCTAGCCTT 480
481 GAAGAACCCATTTACGCTCAAGTTGCTAAAAAGGTAAATGCAAAAATTGACCGACTCAAT 540
541 CAAATAGCAAGTGGTTTGGGTGTTGTAGGGCAAGCAGCGGGCTTCCCTTTGAAAAGGCAT 600
601 GATAAAGTTGATGATCTCAGTAAGGTAGGGCTTTCAAGGAATCAAGAATTGGCTCAGAAA 660
661 ATTGACAATCTCAATCAAGCGGTATCAGAAGcgaattc 699
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Status of Claims

3) Claims 45, 54, 57, 62, 70, 81, 123, 141, 142, 147, 154, 159, 166 and 169 have been amended via the amendment filed 10/12/05.

Claims 126, 128, 170 and 171 have been canceled via the amendment filed 10/12/05.

Claims 45, 54, 57, 62, 68, 81, 123, 141, 142, 147, 154, 159, 166 and 169 have been amended via the amendment filed 02/16/06.

Claims 54, 57, 63, 70, 81, 123, 147, 154, 159, 166, 169, 172 and 176 have been amended via the amendment filed 06/22/06.

Claims 40, 41, 45, 54, 57, 59, 62, 63, 68, 70, 78, 80, 81, 88, 123, 127, 140-169 and 172-180 are pending and are under examination.

Substitute Sequence Listing

4) Acknowledgment is made of Applicants' substitute sequence listing filed 06/22/06, which has been entered on 06/26/06.

Objection(s) Withdrawn

5) The objection to claims 166 and 169 made in paragraph 30 of the Office Action mailed 07/28/05 is withdrawn in light of Applicants' amendments to the claims.

Rejection(s) Withdrawn

- 6) The rejection of claims 57 and 59 made in paragraph 33 of the Office Action mailed 11/30/04 and maintained in paragraph 27 of the Office Action mailed 07/28/05 under 35 U.S.C § 103(a) as being unpatentable over Cover *et al.* (US 5,403,924 - Applicants' IDS) ('924) and Dunn *et al.* (*Infect. Immun.* 60: 1946-1951, May 1992 - Applicants' IDS) or Evans *et al.* (*Infect. Immun.* 60: 2125-2127, May 1992 - Applicants' IDS) in view of Hirschl *et al.* (*In: Helicobacter pylori, gastritis and peptic ulcer.* (Ed) Malfertheiner *et al.* Springer-Verlag, Berlin Heidelberg, 141-146, 1990), is withdrawn in light of Applicants' amendment to the base claim.
- 7) The rejection of claims 70, 80, 167 and 168 made in paragraph 34 of the Office Action mailed 11/30/04 and maintained in paragraph 28 of the Office Action mailed 07/28/05 under 35 U.S.C § 103(a) as being unpatentable over Cover *et al.* (US 5,403,924 - Applicants' IDS) ('924) and Cover *et al.* (US 6,054,132, filed 02/26/1992) ('132) in view of Hirschl *et al.* (*In: Helicobacter pylori, gastritis and peptic ulcer.* (Ed) Malfertheiner *et al.* Springer-Verlag, Berlin Heidelberg, 141-146, 1990, already of record), is withdrawn in light of Applicants' amendment to the base claim.
- 8) The rejection of claims 164 and 165 made in paragraph 28 of the Office Action mailed 07/28/05 under 35 U.S.C. § 103(a) as being unpatentable over Cover *et al.* (US 5,403,924 - Applicants' IDS) ('924) as modified by Dunn *et al.* (*Infect. Immun.* 60: 1946-1951, May 1992 - Applicants' IDS) or Evans *et al.* (*Infect. Immun.* 60: 2125-2127, May 1992 - Applicants' IDS) in view of Hirschl *et al.* (*In: Helicobacter pylori, gastritis and peptic ulcer.* (Ed) Malfertheiner *et al.* Springer-Verlag, Berlin Heidelberg, 141-146, 1990, already of record) as applied to claim 57, is withdrawn in light of Applicants' amendment to the base claim.
- 9) The rejection of claims 45, 54, 62, 68, 78, 81 and 88 made in paragraph 20 of the Office Action mailed 06/10/04 and maintained in paragraph 25 of the Office Action mailed 11/30/04 and paragraph 24 of the Office Action mailed 07/28/05 under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (*PNAS* 90: 5791-5795, June 1993 - Applicants' IDS), is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s), amendments to the specification, and Applicants' arguments.
- 10) The rejection of claims 45, 54, 62 and 81; claims 68, 78, 88, 152 and 153 dependent therefrom; and claims 141, 142, 147, 154, 159 and those dependent therefrom, made in paragraph in paragraph 28 of the Office Action mailed 11/30/04 and maintained in paragraph 25 of the Office

Action mailed 07/28/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s), amendments to the specification, and Applicants' arguments.

11) The rejection of claim 123 made in paragraph in paragraph 29 of the Office Action mailed 11/30/04 and maintained in paragraph 26 of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn.

12) The rejection of claim 123 made in paragraph 20 of the Office Action mailed 06/10/04 and maintained in paragraph 25 of the Office Action mailed 11/30/04 and paragraph 24 of the Office Action mailed 07/28/05 under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (PNAS 90: 5791-5795, June 1993 - Applicants' IDS), is withdrawn in light of the amendment made to the claim.

Remarks

13) Claims 40, 41, 45, 54, 57, 59, 62, 63, 68, 70, 78, 80, 81, 88, 123, 127, 140-169 and 172-180, now renumbered as claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17-46 and 47-55 respectively, are allowed.

The amendments made to the paragraph beginning at line 12 of page 6 of the specification and the amendment made to claim 123 have descriptive support at lines 22-38 of page 6, page 7 particularly at lines 17-29, page 9, and Figure 3 of the English translated foreign priority document, FI92 A 000052, the entire contents of which foreign priority application were incorporated by reference via the preliminary amendment filed 07/26/99. The term 'purified' that is added by Applicants to claims 154, 159, 166 and 169 has descriptive support at lines 19-29 of page 16 of the specification.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

15) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

Serial Number: 09/360,685
Art Unit: 1645
June 2006

see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

July, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER